

Notice of Allowability

Application No.

10/673,671

Applicant(s)

SASTRY ET AL.

Examiner

Nicole E. Kinsey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2-19-2007.
2. ☒ The allowed claim(s) is/are 75-99.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

75. A method of treating an HIV-infected human subject, the method comprising the steps of administering to said subject a pharmaceutically acceptable composition which delivers one or more peptides having peptide sequences selected from the group consisting of the following groups of peptide sequences or combinations thereof:

- a) SEQ ID NO:26, 27, 28, 29, 30, 31, 32, 33 or 34;
- b) SEQ ID NO:20, 21, 22, 23, 24, 25 or 40;
- c) SEQ ID NO:1, 2 or 3;
- d) SEQ ID NO:4, 5, 6, or 7;
- e) SEQ ID NO:8, 9, 10, 11, 12, 13, 14, 15 or 38; and
- f) SEQ ID NO:16, 17, 18, 19 or 20;

wherein the delivery of said peptide(s) promotes the induction of an HIV-directed cytotoxic T-lymphocyte response.

76. The method of claim 75, further comprising determining before or after said administration whether said subject exhibits an HLA-Cw7-restricted CTL response.

80. The method of claim 75, wherein a plurality of peptide sequences are delivered to said subject comprising at least two peptide sequences, one selected from each of the following two groups of peptide sequences:

- (a) SEQ ID NO:26, 27, 28, 29, 30, 31, 32, 33 or 34; and
- (b) SEQ ID NO: 1, 2 or 3.

81. The method of claim 75, wherein a plurality of peptide sequences are delivered to said subject comprising at least two peptide sequences, one selected from each of the following two groups of peptide sequences:

- (a) SEQ ID NO:8, 9, 10, 11, 12, 13, 14, 15 or 38; and
- (b) SEQ ID NO:16, 17, 18, 19 or 39.

84. The method of claim 83, wherein the plurality of peptide sequences delivered to said subject comprises at least five peptide sequences, one selected from each of the following five groups of peptide sequences:

- (a) SEQ ID NO:26, 27, 28, 29, 30, 31, 32, 33 or 34;
- (b) SEQ ID NO:20, 21, 22, 23, 24, 25 or 40;
- (c) SEQ IDNO:1, 2 or 3;
- (d) SEQ ID NO:4, 5, 6 or 7; and

(e) SEQ ID NO:8, 9, 10, 11, 12, 13, 14, 15,38, 16, 17, 18, 19 or 39.

96. The method of claim 75, wherein the subject does not exhibit an HLA-Cw7-restricted CTL response, further comprising:

- (a) determining before or after said administration if the subject expresses the HLA-Cw7 haplotype; and if so,
- (b) eliciting said response.

Delete the paragraph on page 11, lines 21-29, and replace with the following paragraph.

FIG. 8A-E. Post-challenge analysis of blood samples from control and vaccinated monkeys. Post-challenge analysis of blood samples showing efficient control of SHIV infection in the vaccinated monkeys compared to the control animals. Blood samples were collected from the monkeys at different time intervals after challenge with SHIV-ku2, and analyzed for total CD4+ cells by flow cytometry and shown as absolute numbers (CD4+ cells). A series of 10-fold serial dilutions of PBMC isolated from the blood samples were co-cultured with 10^6 C8166 indicator cells in 24-well tissue culture plates, and the highest dilution of PBMC showing a visible cytopathic effect (CPE) was used to calculate the number of SHIV-infected cells (SHIV+ cells) per 10^6 PBMC.

Delete the paragraph beginning on page 76, line 22, and ending on page 77, line 2, and replace with the following paragraph.

T-helper peptides may also be coadministered with the HIV polypeptides, peptides, or their corresponding nucleic acid sequences of the present invention to improve CTL induction (Del Guercio *et al.*, 1997; Mortara *et al.*, 1999). For example, a lipopeptide that includes a promiscuous human helper T cell (Th) epitope from a tetanus toxoid peptide increased a CTL induction response to various SIV peptides (Mortara *et al.*, 1999). The sequence of this peptide (aa 830 - aa 846) had a lipid moiety attached at one end. Other T-helper promiscuous peptides can be used in the methods of the invention such as PADRE epitopes, which have been characterized as binding to different HLA-DR entities (Del Guercio, *et al.*, 1997).

Authorization for this examiner's amendment was given in a telephone interview with David Parker on February 28, 2007.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

A handwritten signature in cursive script, reading "Bruce Campell".

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600